

REMARKS

Status of the Claims

Claims 1,2, and 4-25 are currently pending in the application. Claims 7-23 are withdrawn from consideration as directed to a nonelected invention. Claims 1, 2, 4-6, 24, and 25 were rejected. Claim 1 has been amended. No new matter has been added.

Restriction Requirement

Applicants respectfully submit that the restriction of the invention is improper and should be withdrawn. In particular, the application contains a single general inventive concept, namely a discrete powder comprising particles of a matrix of a polymeric material encapsulating droplets of biliquid foam, as recited in elected claims 1, 2, 4-6, and 24-25. Withdrawn claims 7-17 are directed to methods of making the claimed discrete powder and should be rejoined in the present application because they recite the same special technical feature.

Reconsideration and withdrawal of the restriction requirement are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

A. The Examiner rejected claim 1 under 35 U.S.C. §103(a) as allegedly being unpatentable over the combined teachings of U.S. Patent No. 3,549,555 to Hiestand et al. (hereinafter “Hiestand”) and U.S. Patent No. 4,999,198 to Barnett et al. (hereinafter “Barnett”) further in view of U.S. Patent No. 3,016,308 to Macaulay (hereinafter “Macaulay”) and U.S. Patent No. 6,165,479 to Wheeler (hereinafter “Wheeler”). Applicants respectfully traverse the rejection for the reasons already of record as well as those presented below.

The test for determining if a claim is rendered obvious by one or more references for purposes of a rejection under 35 U.S.C. § 103 is set forth in *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007):

"Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented." Quoting *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966).

As set forth in MPEP 2143.03, to ascertain the differences between the prior art and the claims at issue, "[a]ll claim limitations must be considered" because "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385. According to the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in view of *KSR International Co. v. Teleflex Inc.*, Federal Register, Vol. 72, No. 195, 57526, 57529 (October 10, 2007), once the *Graham* factual inquiries are resolved, there must be a determination of whether the claimed invention would have been obvious to one of ordinary skill in the art based on any one of the following proper rationales:

(A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try"—choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations would have been predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 550 U.S.398, 82 USPQ2d 1385 (2007).

Furthermore, as set forth in *KSR International Co. v. Teleflex Inc.*, quoting from *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006), “[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasonings with some rational underpinning to support the legal conclusion of obviousness.”

Therefore, if the above-identified criteria and rationales are not met, then the cited reference(s) fails to render obvious the claimed invention and, thus, the claimed invention is distinguishable over the cited reference(s). Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness because the references, alone or in combination, fail to teach or suggest all the claim elements.

1. Hiestand

Hiestand is directed to a process for encapsulating a hydrophobic liquid in aqueous emulsion with a wall-forming polymeric material, wherein the wall-forming material is hardened. Col. 1, lines 18-23. To be clear, Hiestand teaches a hardened capsule with three phases, the core material and two liquid phases. Col. 1, lines 54-65 and col. 2, lines 17-22. Hiestand teaches that the finally treated coacervate can be dried to produce a product essentially free of surface moisture. Col. 7, lines 20-22.

Hiestand does not teach or suggest a discrete powder. The teaching of a capsule that is essentially free of surface moisture is not a teaching or suggestion of a discrete powder. Moreover, the Examiner has acknowledged that Hiestand does not

teach or suggest the powder particles having a mean size of 5 to 150 μm . See Office Action dated February 18, 2009 at 6 and July 31, 2009 at 7. .

The Examiner has also acknowledged that Hiestand does not teach or suggest a biliquid foam. Office Action dated July 31, 2009, at 3 and 7. Because Hiestand does not teach or suggest a biliquid foam it certainly does not teach or suggest the biliquid foam droplets having a mean size of 1 to 45 μm . *Id.* Moreover, Hiestand does not teach or suggest a matrix of polymeric material encapsulating droplets of biliquid foam. At most, Hiestand teaches encapsulating a double emulsion, but fails to teach or suggest all of the elements of the claimed invention.

2. Barnett

The Examiner relied on Barnett for teaching a polyaphron having a continuous phase and a disperse phase, wherein the disperse phase comprises a drug. Abstract. Barnett also teaches that the release rate of the drug can be controlled by polymerization of either phase, such as by the addition of monomers to the oil and water phase to obtain polymerization at the interface for release control. Col. 3, lines 55-60. However, this is not a teaching or a suggestion of matrix of polymeric material encapsulating droplets of biliquid foam. To be clear, there is no teaching or suggestion in Barnett of a matrix of polymeric material encapsulating droplets.

Barnett does not overcome the deficiencies of Hiestand. Barnett does not teach or suggest a discrete powder, let alone the powder particles having a mean size of 5 to 150 μm , as presently recited.

Barnett does not teach or suggest particles of a matrix of a polymeric material encapsulating droplets of biliqid foam, let alone that the biliqid foam droplets have a mean size of 1 to 45 μm , as presently recited.

At most, Barnett teaches a biliqid foam having a continuous and a disperse phase. However, this is not a teaching or suggestion of all of the claim elements and certainly does not overcome the numerous deficiencies of Hiestand.

The Examiner has argued that it would have been obvious to substitute the drug-loaded polyaphron composition of Barnett for the drug-loaded, oil-in-water emulsion which is coated in Hiestand. Office Action dated July 31, 2009 at 8. The Examiner argued that one would be motivated to make this substitution because the two compositions are chemically homologous. *Id.*

First, of all, such a substitution still does not teach or suggest all of the claim elements. In particular, the substitution still fails to teach or suggest a discrete powder, let alone the powder particles having a mean size of 5 to 150 μm , as presently recited. Moreover, the substitution still fails to teach or suggest biliqid foam droplets having a mean size of 1 to 45 μm , as presently recited.

Second, the Examiner's rationale for making the proposed substitution is incorrect, i.e., that the two compositions are chemically homologous. Applicants have spent considerable time explaining to the Examiner via arguments and additional references, such as the Annex filed with the May 18, 2009, response, that a biliqid foam is not chemically homologous to an emulsion. They are not made the same, their chemical structure is not the same, there chemical and physical properties are not the same. So, the Examiner's comment that the two compositions, i.e., the three phase

emulsion of Hiestand and the biliquid foam of Barnett, are the same is without merit. In fact, the Examiner acknowledged that they are distinct compositions in the present Office Action at page 5, i.e., “[p]olyaphrons and emulsions are taught in the art as being distinct compositions.” For at least this reason, the skilled artisan would not have a reasonably high expectation that both compositions could be encapsulated as taught by Hiestand.

Moreover, Hiestand uses encapsulation because he is trying to “maintain the hydrophobic liquid in aqueous emulsion in isolation from a contiguous environment” or “to control the release of the emulsion through its capsular wall.” Barnett, which was invented almost 20 years later, surely had heard about encapsulation, yet decided the best way to control the release rate of its drug was via polymerization of the oil and/or water phase by addition of monomers. One of skill in the art would likely not look to Hiestand for encapsulating the biliquid foam of Barnett because the *hardening* of the coacervate wall in Hiestand would likely detrimentally affect the biliquid foam droplets of Barnett.

Moreover, one of ordinary skill in the art would not have any reason to expect that the coacervating materials of Hiestand, which work with emulsions, would also work with a biliquid foam because, as acknowledged by the Examiner and discussed in the response filed on May 18, 2009, there is a single interface in an emulsion and a double interface in a biliquid foam. For at least this reason, one of ordinary skill in the art has no reasonable expectation of successfully encapsulating the biliquid foam of Barnett using the coacervating materials of Hiestand.

3. Macaulay

Macaulay is directed to recording paper coated with microscopic capsules of coloring material. The discrete capsules which make up the free-flowing powder of the invention possess a shell or wall containing therein a marking fluid. Col. 1, lines 10-15. The shell is non-permeable and remains intact and retains the fluid within until substantial pressure is applied. Col. 3, lines 48-50.

The Examiner has acknowledged that Macaulay does not teach or suggest the powder particles having a mean size of 5 to 150 μm , as presently recited. Office Action dated February 18, 2009 at 6.

The Examiner has also acknowledged that Macaulay does not teach or suggest a biliquid foam. Office Action dated July 31, 2009, at 4. Because Macaulay does not teach or suggest a biliquid foam it certainly does not teach or suggest the biliquid foam droplets having a mean size of 1 to 45 μm . *Id.* Moreover, Macaulay does not teach or suggest a biliquid foam comprising a continuous phase and a disperse phase, as presently claimed.

The Examiner relied upon Macaulay for teaching particles containing a dispersible liquid having a particular size. Office Action dated March 11, 2009, at 7. However, the teaching of particles containing a dispersible liquid having a particular size is not a teaching or suggestion of droplets of biliquid foam having the claimed size. Moreover, it is not a teaching or suggestion of powder particles having the claimed size.

For at least these reasons, Macaulay does not overcome the deficiencies of Hiestand and/or Barnett.

4. Wheeler

Wheeler teaches that the advantage of using a biliqid foam over an emulsion stems from the basis that biliqid foams are less irritating to the skin as compared to emulsions because of their lower level of surfactants. Office Action dated July 31, 2009, at 9 citing col. 2, lines 25-32 of Wheeler. The Examiner relied on Wheeler for teaching a biliqid foam with a pharmaceutical and/or cosmetic composition embedded therein. Office Action dated July 31, 2009, at 9. However, Wheeler does not teach or suggest all of the claim elements and does not overcome the deficiencies of the references discussed above.

Wheeler does not teach or suggest a discrete powder of that the powder particles having a mean size of 5 to 150 μm . Wheeler does not teach or suggest biliqid foam droplets having a mean size of 1 to 45 μm . Moreover, Wheeler does not teach or suggest a matrix of polymeric material encapsulating droplets of biliqid foam.

For the same reasons discussed above with regard to combining the teachings of Hiestand and Barnett, one of skill would not combine the teachings of Hiestand and Wheeler. Moreover, such a combination would still not teach or suggest all the claim elements.

One of skill would not combine Barnett and Wheeler because such a combination would not lead to the claimed invention comprising a powder comprising particles of a matrix of polymeric material encapsulating a biliqid foam.

For at least all of the reasons discussed above, the Examiner has failed to establish a *prima facie* case of obviousness because the references, alone or in combination, fail to teach or suggest all the claim elements. Moreover, one of ordinary

skill in the art would not be motivated to combine the teachings of encapsulating an emulsion with teachings of biliquid foam with a reasonable expectation of success.

Reconsideration and withdrawal of the rejection are respectfully requested.

B. The Examiner rejected claims 2 and 4 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hiestand with respect to claim 1, as set forth above. Applicants respectfully traverse the rejection for the reasons already of record as well as those presented below.

Claims 2 and 4 depend from independent claim 1 and are patentable for at least the same reasons as claim 1. In particular, the Examiner has admitted on several occasions, as discussed above, that Hiestand does not teach or suggest a biliquid foam, let alone biliquid foam droplets having a mean size of 1 to 45 µm. Moreover, the Examiner has admitted that Hiestand does not teach or suggest a discrete powder, let alone discrete powder particles having a mean size of 5 to 150 µm. To be clear, Hiestand does not teach or suggest powder particles of a polymeric material encapsulating biliquid foam droplets.

For at least these reasons, Hiestand does not render obvious the claimed invention because it does not teach or suggest all the claim elements. Reconsideration and withdrawal of the rejection are respectfully requested.

C. The Examiner rejected claims 5, 6, 24, and 25 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hiestand with respect to claim 1 as set forth above, as further evidenced by Wheeler. Applicants respectfully traverse the rejection for the reasons already of record as well as those presented below.

Claims 5, 6, 24, and 25 depend from independent claim 1 and are patentable for at least the same reasons as claim 1. Hiestand, and its deficient teachings, have been discussed at length above. However, Wheeler does not overcome these deficiencies of Hiestand.

For at least these reasons, the references, alone or in combination, do not render obvious the claimed invention because they do not teach or suggest all the claim elements. Reconsideration and withdrawal of the rejection are respectfully requested.

Conclusion

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration of this application and the timely allowance of the pending claims. This is believed to be a complete and proper response to the Examiner's Office Action.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 50-3290.

Respectfully submitted,

Dated: August 11, 2010

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